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EXAMINER	
PREBILIC, PAUL B	
ART UNIT	**PAPER NUMBER**
3738	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,172	GLOBERMAN ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

On page 1, the continuing data is not clear because it is not clear how the parent application is related to PCT/IB98/00523. To be related, there should be a continuation, a continuation-in-part, or a divisional relationship between them. It is noted that the original specification referred to this PCT application as a continuation parent application to the present application.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 107, 108, 113-115 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claims 107, 108 and 113-115, Applicant fails to disclose information referring to "surface fill factor" and "axially dense" in the specification sufficiently enough for one skilled in the art to understand the claimed subject matter.

The amendment filed June 16, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment

shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows:

The insertion made to page 51, line 33 changes the meaning of the original specification because it attempts to define "surface fill factor" in a manner that does not have clear original basis in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8, 10, 12-16, 19-30, 46, 48, 51, 52-55, 57, 58, 60-62, 66, 68, 69, 70, 72, 80, 92, 93, 95, 103, 106-112, and 122-124 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (USPN 5,059,193).

Regarding claims 1-4 and 30, Kuslich discloses of an axial tube (Fig. 3, Ref. Num. 12) with a plurality of straight slits (Ref. Num. 24) that define at least four extensions and defines the geometry of an expanded spacer when axially compressed (Fig. 1).

Regarding claims 6-8 and 10, Kuslich discloses slits of the same length that are parallel to the axis of the tube, are cut in the tube, and defined by a section removed from the body of the tube.

Regarding claim 12, Kuslich discloses slits that are symmetric across the tube axis and thus overlap.

Regarding claims 13-16, Kuslich discloses end caps that are flush against the expanded extensions (Fig. 3, Ref. Num. 18 and 14).

Regarding claims 19-26, Kuslich discloses an inner bolt or tie rod with a smooth and threaded exterior (Fig. 1, Ref. Num. 14) with a base (Ref. Num. 18) of larger diameter than the inner diameter of tube (Ref. Num. 12).

Regarding claims 27-29, Kuslich discloses that the spacer is implanted with a ratchet gun, which comprises a barrel or pole element (Fig. 2, Ref. Num. 118) for holding the bolt or tie rod during deployment. The bolt is threaded for engaging the pole element or barrel of the ratchet gun.

Regarding claims 46, 48, 66 and 68 Kuslich discloses that the extensions are evenly distributed about the straight axis and circumference of the tube (Figure 1).

Regarding claims 51, 52-55, 57, 58, 60, 61 and 62 Kuslich discloses that the axis of the expanded geometry of the spacer is coaxial and parallel to the tube axis. The tube axis, not being explicitly defined, could be along the surface of the device and thus the tub axis is not parallel to the axis of the expanded geometry. Kuslich further teaches that the cross-section of the expanded geometry is circular and varies in

diameter along the axis (Figure 1), and the cross-section of the tube is circular (Figure 3).

Regarding claim 69 and 70, Kuslich discloses a ratchet to maintain the expander in an expanded configuration, where the distal and proximal ends of the spacer contact the end caps of the bolt of the ratchet to prevent axial contraction of the spacer.

Regarding claim 72, Kuslich discloses inner ribs that help the spacer maintain it's arched shape and thus form a thickness that prevents the opposing sides from meeting. The material exhibits the quality of being foldable since it is capable of being arched.

Regarding claim 80, Kuslich discloses an expandable spacer where the extensions lift-up away from the tube to form the expanded geometry (Figure 1).

Regarding claims 92, 93 and 95, Kuslich discloses that the expandable spacer can be made of metal, plastic (polyethylene) or different materials (Column 4, Lines 59-64).

Regarding claim 103, Kuslich teaches that the expandable spacer can be implanted in the spine with the tube axis perpendicular to the axis of the human spine (Figure 2).

Regarding claims 106-112, Kuslich discloses that the expandable spacer that is sized to fit between two vertebrae (Column 6, lines 45-68) and has extensions where the tips or outer shell (Fig. 1, Ref. Num. 26) fill at least 40% of the space and cover at least 80% of the contacting disc.

Regarding claims 122-124, Kuslich discloses that the spacer is implanted in a bore made within the vertebral bone (Column 6, Lines 45-68) and is lordotic (Column 7, lines 13-29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 9, 11, 45, 47, 49, 50, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (USPN 5,059,193).

Regarding claims 5 and 9, Kuslich discloses an expandable spacer where the slits are straight and parallel to the tube axis. Kuslich does not disclose expressly that the slits are curved.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make an expandable spacer with curved slits that are not parallel to the tube axis because Applicant has not disclosed that curved slits provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with curved slits that are not parallel to the tube axis as long as the slits define extensions.

Therefore it would have been an obvious matter of design choice to modify the invention of Kuslich to obtain the invention as specified in claims 5 and 9.

Regarding claims 63 and 64, Kuslich discloses a tube with a circular cross-section. Kuslich does not disclose expressly a tube with a rectangular or elliptical cross-section.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a tube of elliptical or rectangular cross-section because Applicant has not disclosed that an elliptical or rectangular tube cross-section provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with an elliptical or rectangular cross-section because the tube is still capable of being expanded.

Therefore it would have been an obvious matter of design choice to modify the invention of Kuslich to obtain the invention as specified in claims 63 and 64.

Regarding claims 11, 45, 47, 49 and 50, Kuslich does not disclose expressly slits in pairs of different lengths or that the extensions are unevenly distributed or have different geometries.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have slits of different length and unevenly distributed extensions because Applicant has not disclosed that slits of different length or extensions that are unevenly distributed with different geometries provide an advantage, is used for a particular purpose, or solves a stated problem. One

of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with pairs of slits of different lengths and extensions that are unevenly distributed with different geometries because the extensions would still be capable of being expanded.

Therefore it would have been an obvious matter of design choice to modify the invention of Kuslich to obtain the invention as specified in claims 11, 45, 47, 49 and 50.

Regarding claim 72, Kuslich teaches of an inner ribs that help the pacer maintain it's arched shape and thus form a thickness that prevents the opposing sides from meeting.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (USPN 5,059,193) in view of Pisharodi (USPN 5,123,926).

Regarding claims 17 and 18, Kuslich discloses an expanded spacer but lacks the teaching of spurs on the spacer. Pisharodi teaches of an artificial spine prosthesis with spurs (Fig. 3, Ref. Num. 8) to hold the prosthesis within the intervertebral disk space. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to have spurs on the outside of the spacer to hold it in place.

Claims 31-44, 56, 59, 75, 77-79, 81-83, 84, 86-88, 90, 91, 98-102 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (USPN 5,059,193) in view of Drewry et al. (USPN 6,149,651).

Regarding claims 31-44, 81-83, 84, 86-88 and 120, Kuslich discloses an expanded spacer with segments defining extensions however he lacks the teaching of

segments that extend in different directions. Drewry et al. teach of a bone spacer that has at least four segments extending at various angles, including 45 and 90 degrees to the axis or the tube, joined at an extension top or joint, and forming a triangular and curved profile (Figure 1 and 7) in order to dissipate the load pressure exerted on the prosthesis. Drewry et al. further teach that the spacer has at least two legs aligned (perpendicularly) with the tube axis (Column 3, lines 16-20) and a plurality of holes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to have segments extending in different directions to enhance the spacer's ability to distribute the forces that will be exerted on the spacer.

Regarding claims 56 and 59, Kuslich lacks a spacer with a rectangular cross-section. Drewry et al. teach of a bone spacer that can have a non-circular cross-section (Column 5, lines 33-41) in order to conform to the various shapes of the bone being supported. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to have a spacer with a non-circular cross-section to conform to the various shapes of the intervertebral space.

Regarding claims 75 and 77-79, Kuslich lacks the teaching of interconnecting elements and joints. Drewry et al. teach of a bone spacer with segments that are joined by interconnecting elements (Fig. 1, Ref. Num. 25) and joints (Fig. 1, Ref. Num. 30) to provide substantial axial, torsional and bending strength (Column 3, Lines 20-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the invention of Kuslich to include joints between the segments to enhance he axial, torsional and bending strength of the spacer. Regarding claims 91 and 98-102, Kuslich teaches that the spacer could be made of plastic or ceramic but lacks teaching that the spacer is made of metal. Drewry et al. teach of a bone spacer that could be made of metal and is strong enough to withstand the application of external compressive forces (Column 5, Line 56-Column 6). The external compressive forces of an average male is about 70 kg (187 lbs.), so it would be expected that the spacer is capable of being deformed under greater pressure, over 90 kg. Regarding claim 90, the ability of an implant to be deformed under pressure means that it is capable of changing its axial length (i.e. expanding axially and compressing radially due to forces) due to the pressure over time.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to make the spacer out of metal so that it could be axially deformed, including a change in length, under pressures over 90 kg.

Claims 65, 67, 76, 85, 89, 94, 96, 97, 116 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (USPN 5,059,193) in view of Penn et al. (USPN 6,217,608).

Regarding claims 65, 67 and 121, Kuslich discloses an expandable spacer but lacks the teaching that the tube axis is bent when the spacer is expanded or unexpanded. Penn et al. teach of an expandable spacer with a bent axis when the spacer is expanded or unexpanded to allow it to fit within various lumen (Figure 11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to have the tube axis of bent when the spacer is expanded or unexpanded to allow the spacer to fit into bone defect areas of different shapes and sizes.

Regarding claims 76, 85, 89, 94, 96 and 97, Kuslich lacks teaching that the spacer is made from an elastic or super-elastic material. Penn et al. teach of an expandable spacer that could be made of the super-elastic, shape memory metal alloy nitinol (Column 13, Lines 45-50) that is flexible and capable of self-expanding, eliminating the need for additional expansion means. It is well known that nitinol is an annealed alloy. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to make the spacer of a super-elastic material such as nitinol so that the implant could self-expand once positioned within the intervertebral space.

Regarding claim 116, Kuslich lacks the teaching of a bioactive coating on the spacer. Penn et al. teach of a coating on the spacer for the delivery of pharmaceutical agents (Column 7, Lines 1-8). Therefore, it would have been obvious to put a coating on the spacer of Kuslich for the same reasons that Penn did the same.

Claims 104 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (USPN 5,059,193) in view of Dinh et al. (USPN 6,019,789).

Regarding claims 104 and 105, Kuslich does not expressly disclose that the diameter of the tube is smaller than 4 times the diameter of the expanded geometry. Dinh et al. teach of an expandable spacer where the ratio of expanded to unexpanded

diameter is between 1-10 (Column 2, Lines 40-55) to allow the spacer to be easily implanted at the reduced diameter and expand to the diameter necessary to maintain vessel patency. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to have the diameter of the tube smaller than 4 times the diameter of the expanded geometry to allow for ease of insertion prior to expansion.

Claims 117 and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (USPN 5,059,193) in view of Penn et al. (USPN 6,217,608) in further view of Drewry et al. (USPN 6,149,651).

Regarding claims 117 and 118, Kuslich and Penn et al. teach of expandable spacers but lack the teaching of including a bone growth inducing or retarding agent on the spacer. Drewry et al. teach of including an osteoinductive material within the gaps of the spacer (Column 6) to promote the growth of natural bone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to have an agent that will affect the growth of bone around or within the spacer.

Claim 119 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (USPN 5,059,193) in view of Pisharodi (USPN 5,123,926).

Regarding claim 119, Kuslich teaches of an expandable spacer but lacks the teaching of the spacer having extensions with spikes. Pisharodi teaches of a spinal prosthesis with spikes to engage the vertebrae upon implantation (Fig. 1, Ref. Num. 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the invention of Kuslich to include spikes on the extensions of the spacer to secure the spacer once implanted.

Claims 71, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (USPN 5,059,193) in view of Picha et al. (USPN 5,876,457).

Regarding claims 71, 73 and 74, Kuslich lacks the teaching of tabs that extend to prevent axial contraction. Picha et al. teach of a spinal implant or spacer with extensions or threads (Fig. 1, Ref. Num. 12) that include tabs or protrusions (Fig.s 4-11) to assist in securing the implant to the vertebra material. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kuslich to have protrusions on the extensions in order to secure the implant in place within the vertebra.

Response to Arguments

Applicant's arguments filed June 16, 2003 have been fully considered but they are not persuasive.

The changes made to the specification and claims were sufficient to overcome the specification and claim objections of the previous Office action.

In response to the traversal of the 35 USC 112, first paragraph rejection, the Examiner asserts that the manner in which "surface fill factor" was inserted into the specification attempts to add new matter thereinto. For this reason, an objection has been made to the specification pertaining to this issue. In referring to the specification on page 15, the Examiner notes that the language used therein is the same as that

used in the original specification; it fails to clarify the meaning of the terminology. For this reason, the claim terminology lacks an adequate written description.

With regard to the "axially dense" language, the original claim language does not define this terminology as meaning the density of the extensions in the axial direction. Rather, the terminology is unclear.

In response to the traversal of the 35 USC 102 and 103 rejections that Kuslich does not disclose two axially displaced extensions, the Examiner asserts that since the axes have not been defined that Kuslich reads on the claimed invention. This is because the axes can be along the surface of the tube and define different ribs (26, 28) or extensions of Kuslich's implant. For this reason, the Examiner asserts that the claim language is fully met by Kuslich.

Similarly, since Applicant relied upon 35 USC 102 traversal to traverse the 35 USC 103 rejections, the Examiner asserts that these rejections are also tenable because the 35 USC 102 rejection is tenable. For this reason, the 35 USC 103 rejections of record have been maintained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited is viewed as reading on the presently claimed invention, which is drawn merely to "A spacer" or "An expandable spacer." For this reason, the Examiner was unable to find language, which would put the claims in condition for allowance.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure

outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738